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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO
09/125,122	01/04/99	TARRO G	A31920-PCT-U

EXAMINER

021003
BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK NY 10112

HM12/0317

ART UNIT	PAPER NUMBER
FITZGERALD, D	
1646	9

DATE MAILED: 03/17/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-4, 6 is/are rejected.
☒ Claim(s) 5 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

★ U.S. GPO 1996 404-496/40517

1. This application was filed under the provisions of 35 U.S.C. § 371. The examiner has reviewed and considered the International Search Report (PCT/ISA/210) and the International Preliminary Examination Report (PCT/IPEA/409) prepared during the international stage of this application. Additionally, the references cited in the Search Report, which applicant has cited in an Information Disclosure Statement, have been considered.

2. The application papers are objected to under 37 C.F.R. § 1.52(a) because they are not uniformly legible and are not of sufficient quality to permit xerographic reproduction.

The disclosure is additionally objected to because of multiple informalities too numerous to catalog. Among these are incomplete, awkward, or nonidiomatic translations, *e.g.*, "high amount of active principle" (page 2, line 9); "posology" (page 4, line 2); "as opposite to" (page 4, line 18); "U/die" (page 6, line 24). There are additionally a number of typographical errors, and British rather than American spellings are employed throughout.

A substitute specification incorporating suitable revisions is required. The substitute specification must be accompanied by a statement that it contains no new matter. *See* 37 C.F.R. § 1.125. However, compliance with this requirement may be deferred pending the identification of allowable subject matter.

3. Claims 1 and 2 are objected to under 37 C.F.R. § 1.75(b) as being duplicate claims. The claims appear to be identical in scope and content because they differ only with respect to intended uses for the products made by the claimed "uses." The intended uses *per se* are accorded no patentable weight in construing the claims, and they appear to impose no material or functional limitations on the method steps practiced to make a medicament or on the products produced.

One of the duplicate claims should be canceled or otherwise amended to delimit a different scope of the invention. Applicant's attention is also directed to M.P.E.P. § 706.03(k).

4. Claim 5 is objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim must refer to the claims from which it depends in the alternative only and because a multiple claim may not depend from another multiple dependent claim. See M.P.E.P. § 608.01(n). Accordingly, the claim has not been further treated on the merits.

5. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

6. Claims 1-4 are rejected under 35 U.S.C. § 101 because they are directed to nonstatutory subject matter.

All of claims 1-4 are directed to a "use," a legal creature which does not correspond to one of the classes of invention enumerated in § 101.

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention.

8. Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The noted claims are directed to the "use" of specified products but do not set forth any steps required in the method or process. It is consequently unclear what method or process applicant intends to claim. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how the use is to be practiced. See, for example, *Ex parte Erlich,* 3 U.S.P.Q.2d 1011 (Bd. Pat. App. Int. 1986).

Claims 1-4 are additionally indefinite because it is not clear whether "dosages comprised between . . ." is intended to limit the dosages to the recited ranges or, alternatively, the equivalent of "comprising" is intended.

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Cummins, U.S. Patent No. 5,824,300, or Cummins, WO 88/03411.

Each of the Cummins references describes aqueous formulations of human α interferon (IFN-α) which are suitable for use in the therapeutic methods it describes and claims. *See* '300 at col. 3; '411 at pages 5-6; and the claims of each. Such methods call for delivery to the oropharyngeal mucosae of IFN in solution at dosages preferably ranging from about 0.5 to 1.5 IU per pound per day. '300 at claim 3; '411 at claim 1. For typical patients weighing from about 100 to 225 pounds (*ca.* 45-100 kg), the preferred dosages are thus on the order of 50 to 340 IU IFN-α per day. Among the preferred sources of IFN are buffy coat leukocytes. '300, col. 3, lines 25-35; '311, page 4, liens 2-6. Each of the references teaches that the IFN may be administered once daily or in divided doses. '300 at col. 5, lines 56-61; '311 at the paragraph bridging pages 11-12. Exemplary formulations described by Cummins contain 1-1500 IU of IFN in a dosage volume of one tablespoon (15 ml), or 0.07-100 IU ml^{-1}. '300 at col. 14, lines 1-5; '411 at page 31, first full paragraph. A specific formulation is not described.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare an aqueous solution containing 1-1500 IU of human leukocyte IFN-α in a convenient single-dose delivery volume for oral administration, *e.g.*, 1 tablespoon (15 ml), because Cummins teaches that it is desirable to do so. The concentration range claimed by applicant overlaps the prior art range, and the prior art and the claimed formulations comprise the same active ingredients and are employed in the same manner, *i.e.*, oral delivery in a manner that promotes contact between the IFN solution and the oropharyngeal mucosae. The intended uses recited in the instant claim impose no material or functional limitations on the formulations *per se* or the methods of making them and thus do not patentably define over the prior art formulations.[1] The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

11. Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Cummins '300 or '411 as applied to claims 1, 2, 4, and 6 above, further in view of Ratajczak *et al.*, *Arch. Immunol. Ther. Exp.* 41: 237-40 (1993).

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[1] It is however noted that each of the Cummins references teaches that its formulations are suitable, *inter alia*, for the treatment of viral and neoplastic diseases according to the methods it describes.

The relevant teachings of the Cummins references are as discussed above in connection with the rejections under § 102. Neither describes a formulation employing lymphoblastoid hIFN-α.

Ratajczak describes the use of lozenges containing 50 or 100 IU of human lymphoblastoid IFN-α for oropharyngeal delivery in the treatment of hepatitis B infections. *See* the title and page 239, col. 1, first paragraph.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare an aqueous formulation of hIFN-α according to Cummins '300 or '411, employing lymphoblastoid IFN as described by Ratajczak in place of the buffy coat leukocyte IFN noted particularly by Cummins, because Ratajczak evidences that lymphoblastoid IFN was readily available at the time of the invention and teaches that it is suitable for the treatment of an exemplary viral disease *via* delivery to the oropharyngeal mucosae. It consequently would have been obvious to the artisan that lymphoblastoid IFN would be the functional equivalent of any of the hIFN-α preparations expressly described by Cummins for use in the methods described in the '300 and '411 references. The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone	(703) 308-3934
Fax	
All formal papers	(703) 308-4242
Informal communications	(703) 308-0294
e-mail (note PTO policies below)	david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1600 receptionists at (703) 308-0196.

DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

16 March 2000

The **best time to reach Examiner Fitzgerald** is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the supervisor for this Art Unit, Gary Kunz, may be reached at (703) 308-4623.

Most official papers and all informal **communications may be submitted to the PTO by fax.** For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- Call the examiner when you send an urgent communication.
- **Do not send a duplicate copy** by mail or courier.

Any Internet **e-mail communications will be made of record in the application file**. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.